REMARKS

Claims 1, 2, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 20, 21, 23, 24 and 26-31 are currently in this application. Applicants respectfully request that the examiner enter the amendment cancelling Claim 30 and adding claim 32. Claim 32 defines the extract and does not include the process steps. Claim 32 also defines that the extract is an isolated extract.

Applicants again maintain that all of the claims of this application should be examined in this application. Applicants submit that when claim 32 is allowed that the method claims must be rejoined in this application because a method of treatment using a new and nonobvious extract is new and nonobvious (MPEP 821.04).

The Examiner has rejected claims 30 and 31 under 35 USC 102(b) as anticipated by Thatte or, in the alternative, under 35 USC 103(a) as obvious over Thatte et al. as evidenced by Hoffman and Kruger. Applicants respectfully traverse this rejection.

As stated in the previous response:

> The bane of herbal products is the lack of sufficient standardization in the face of innumerable variables starting from plant species variation through to cultivation processes, plant age at harvesting, season of harvesting and eventually to the process of production of the extract, which is further subject to a whole host of additional variables. For a herbal extract to find commercial or industrial utility in the modern pharmaceutical environment, it is essential to have an extract that has certain parameters reproducible that are considered essential for standardization. This goal has been met with the claimed invention. The standardized extracts must have the properties defined in claim 30-immunomodularity activity and comparision with the peaks of the LC-MS SIR chromatogram.

The extract with properties defined in claim 32 is not disclosed or obvious from the cited references. Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 31 USPQ 1671 (Fed. Cir. 1994). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Found. v. Genentech, Inc.,* 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991). The extract of the claimed invention is not the same as the *Tinospora cordifolia* described in Thatte et al., Kruger and Hoffman. The defined characteristics of the claimed extract are an integral part of the extract and the extract must possess the three criteria included in claim 32. Being an "integral part" would mean that the working of the process claim/s to make the extract must include as additional sub-clauses that the extract obtained would be subjected to further operations to ensure that it fulfills the criteria set for it in claim 32. These criteria have never before been identified for *Tinospora cordifolia* by Thatte, Hoffman, Kruger or anyone else. Evidence prepared by and submitted with the previous response that merely treating the plant material with water at an elevated temperature, and filtering produces extracts may or may not meet the characteristics of claim 32. As shown in that Table 1 submitted with the previous response, there is a failure rate of approximately ca. 40%. The failure to obtain the extract of claim 32 arise due to a number of factors such as the source of the plant material, the location where it is grown, the time at which the plant is collected, the strain variants of TC that may be included in commercial samples, etc. Applicants use LC-MS-SIR to identify the extract of claim 32.

As the Examiner knows, one of the ways to overcome an obviousness rejection is to establish the commercial success due to the invention, failure of others to do what applicants have done; long felt need; etc. *Panduit Corp. v Dennison Mfg. Co.* 1 USPQ 1593 (1987). In order to obtain marketing approval for a drug in the US or Europe, the active ingredients must be standardized. None of the cited references disclose or suggest standardizing an extract of *Tinospora cordifolia*. The Examiner has focused on the process of preparing herbal extracts, but this is really not the issue at all. The extract has the characteristics defined in claim 32. The

process of making it, incorporating the analytical components, establishing and maintaining standard criteria, the compositions made from the extract, and the uses to which it is put, as evidenced by the clinical trials that are described in this specification, distinguish the claimed extract as a novel, exclusive extract and product with defined uses, many of the use different from those previously disclosed.

The extracts of *Tinospora cordifolia* were prepared according to the procedure described in paragraph [00042] of this application. As claimed in claim 32 of this application, the composition comprises an extract of *Tinospora cordifolia* that has one constituent which has a mass spectrometric M+ value of m/z 480 mass units and is present to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass spectrometry single ion recording (LC-MS SIR) chromatogram, and has a second constituent which has a mass spectrometric M+ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified peak areas of the LC-MS SIR chromatogram of the methanol soluble content of said extract. The claimed invention provides for standardization that is neither disclosed nor suggested in the references. There is no disclosure or suggestion of a methanol soluble extract.

In order for a reference to anticipate a claim, a prior art reference must be enabling thus placing the allegedly disclosed matter in the possession of the public. *Akzo v. United States ITC* 808 F.2d. 1471, 1 USPQ2d 1241 (Fed. Cir. 1986). The examiner must be aware that there is no way that the applicants can reproducibly prepare an extract as described by Thatte so as to put it through the criteria used to prepare and identify the extract claimed in claim 32 to establish that the extract claimed in claims 32 and Thatte's differ. Thatte provides no details of the process/es she used. Thatte states that the dried, powdered stem was made into a decoction after boiling in water and administered in the dose of 100 mg/kg/d by intragastric tube. It is unclear from this statement to what the 100 mg refers, whether it is 100 mg decoction or decoction made from 100 mg of dry stem powder. Thatte et al. do not state that the decoction is concentrated or evaporated to provide a powder of which 100 mg is given. Thatte does not describe how long the dried powdered

stem was boiled in water. Thatte does not describe whether the extract was filtered or isolated in some other way. Thatte does not disclose nor suggest that the extract is soluble in methanol. Based on this lack of disclosure, one skilled in the art would expect that the extract of Thatte would contain many different compounds. An advantage of the claimed invention is that there is an extract that is standardized so that it can be incorporated into compositions suitable for use by humans. The extracts of the cited references are not standard and would not receive the required regulatory approval. The criteria set out in claim 32 are not disclosed nor suggested by Thatte.

As stated in the previous response since only the stem is used in Thatte, the extracts cannot be the same. Kruger does not disclose the process used to prepare the claimed composition and does not disclose nor suggest the properties of the claimed extract. Therefore, since the plant components, and the process used to prepare the extracts of this invention are different from what is disclosed in Thatte, Hoffman and Kruger, the claimed invention is novel and nonobvious over Thatte and/or the combination of Thatte, Hoffman and Kruger.

Accordingly, it is respectfully requested that this rejection be withdrawn.

Applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted,

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